

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>	Docket Number 368292000200	Application Number 10/025,514
	Applicant Philip J. BARR et al.	
	Filing Date December 18, 2001	Group Art Unit 1653
	Mailing Date May <u>10</u> , 2002	



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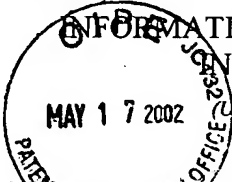
U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	06/11/1985	4,522,811	Eppstein et al.			
	2.	03/22/1988	4,732,973	Barr et al.			
	3.	05/24/1988	4,746,648	Wagnon et al.			
	4.	06/21/1988	4,752,576	Brake et al.			
	5.	07/26/1988	4,760,130	Thompson et al.			
	6.	07/04/1989	4,845,076	Heinzel et al.			
	7.	09/26/1989	4,870,008	Brake			
	8.	10/10/1989	4,873,316	Meade et al.			
	9.	03/03/1992	5,093,316	Lezdey et al.			
	10.	03/01/1994	5,290,762	Lezdey et al.			
	11.	07/12/1994	5,328,470	Nabel et al.			
	12.	11/07/1995	5,464,822	Christophers et al.			
	13.	01/21/1997	5,595,885	Stetler-Stevenson et al.			
	14.	05/27/1997	5,633,227	Muller et al.			
	15.	07/01/1997	5,643,752	Hawkins et al.			
	16.	07/14/1998	5,780,440	Lezdey et al.			
	17.	12/15/1998	5,849,691	Majer et al.			
	18.	12/22/1998	5,851,983	Sugiyama et al.			
	19.	02/16/1999	5,871,956	Bandyopadhyay et al.			
	20.	05/04/1999	5,900,400	Thompson et al.			
	21.	06/22/1999	5,914,392	Hawkins et al.			
	22.	11/16/1999	5,985,309	Edwards et al.			
	23.	01/25/2000	6,017,880	Eisenberg et al.			
	24.	05/30/2000	6,068,994	Barr			
	25.	09/26/2000	6,124,257	Lezdey et al.			
	26.	10/17/2000	6,131,566	Ashurst et al.			

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	27.	10/24/2000	6,136,295	Edwards et al.			
	28.	11/07/2000	6,143,277	Ashurst et al.			
	29.	02/13/2001	RE37,053 E	Hanes et al.			
	30.	07/03/2001	6,253,762 B1	Britto			
	31.	07/03/2001	6,254,854 B1	Edwards et al.			
	32.	09/18/2001	6,291,662 B1	Bandyopadhyay et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	33.	03/09/1983	EP 0 073 657 A1, B1	Europe				
	34.	04/10/1986	WO 86/02100 A1	WIPO				
	35.	06/19/1986	WO 86/03519 A1	WIPO				
	36.	04/20/1988	EP 0 264 166 A1	Europe				
	37.	12/27/1990	EP 0 404 750 B1	Europe				
	38.	04/19/1995	EP 0 648 838 A1	Europe				

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	39.	Agarwal, N. S. and Rich, D. H. (1986). "Inhibition of Cathepsin D by Substrate Analogues Containing Statine and by Analogues of Pepstatin," <i>J. Med. Chem.</i> 29:2519-2524.
	40.	Ausubel, F. M. et al. (2001). <u>Current Protocols in Molecular Biology</u> . John Wiley & Sons, Inc. 11 pages total (Table of Contents for Volumes 1-4 only).
	41.	Aviles, F. X. (1993). <u>Innovations in Proteases and Their Inhibitors</u> . W. DeGruyter, Berlin, N.Y. total pages 5. (Table of Contents).
	42.	Baldwin, E. T. et al. (July 1993). "Crystal Structures of Native and Inhibited Forms of Human Cathepsin D: Implications for Lysosomal Targeting and Drug Design," <i>Proc. Natl. Acad. Sci.</i> 90:6796-6800.
	43.	Banerji, J. et al. (July 1983). "A Lymphocyte-Specific Cellular Enhancer is Located Downstream of the Joining Region in Immunoglobulin Heavy Chain Genes," <i>Cell</i> 33:729-740.

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|-----|---|
| 44. | Barnes, P. J. (February 2000). "Mechanisms in COPD: Differences From Asthma," <i>Chest</i> 117(2):10S-14S. |
| 45. | Barnes, P. J. (July 2000). "Chronic Obstructive Pulmonary Disease," <i>Medical Progress</i> 343(4):269-280. |
| 46. | Barrett, A. J. et al. (1986). "Cysteine Proteinase Inhibitors of the Cystatin Superfamily," Chapter 18 <i>In Proteinase Inhibitors</i> . A. J. Barrett and G. Salvesen eds., Elsevier Science Publishers, pp. 515-568. |
| 47. | Beaucage, S. L. and Caruthers, M. H. (1981). "Deoxynucleoside Phosphoramidites-A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," <i>Tetrahedron Letters</i> 22(20):1859-1862. |
| 48. | Bingle, L. and Tetley, T.D. (1996). "Secretory Leukoprotease Inhibitor: Partnering α_1 -Proteinase Inhibitor to Combat Pulmonary Inflammation," <i>Science Matters</i> 51:1273-1274. |
| 49. | Bode, W. and Huber, R. (1992). "Natural Protein Proteinase Inhibitors and Their Interaction with Proteinases," <i>Eur. J. Biochem.</i> 204:433-451. |
| 50. | Bode, W. and Huber, R. (1994). "Proteinase-Protein Inhibitor Interactions," <i>Fibrinolysis</i> 8 (Suppl. 1):161-171. |
| 51. | Bode, W. and Huber, R. (2000). "Structural Basis of The Endoproteinase-Protein Inhibitor Interaction," <i>Biochimica et Biophysica Acta</i> 1477:241-252. |
| 52. | Boone, T. C. et al. (April 1990). "cDNA Cloning and Expression of a Metalloproteinase Inhibitor Related to Tissue Inhibitor of Metalloproteinases," <i>Proc. Natl. Acad. Sci.</i> 87:2800-2804. |
| 53. | Byrne, G. W. and Ruddle, F. H. (July 1989). "Multiplex Gene Regulation: A Two-Tiered Approach to Transgene Regulation in Transgenic Mice," <i>Proc. Natl. Acad. Sci.</i> 86:5473-5477. |
| 54. | Calame, K. and Eaton, S. (1988). "Transcriptional Controlling Elements in the Immunoglobulin and T Cell Receptor Loci," <i>Adv. in Immunol.</i> 43:235-275. |
| 55. | Camper, S. A. and Tilghman, S. M. (1989). "Postnatal Repression of the α -Fetoprotein Gene is Enhancer Independent," <i>Genes & Dev.</i> 3:537-546. |
| 56. | Carrell, R.W. et al. (July 1982). "Structure and Variation of Human α_1 -Antitrypsin," <i>Nature</i> 298:329-334. |
| 57. | Cawston, T. E. (1995). "Proteinases and Inhibitors," <i>British Medical Bulletin</i> 51(2):385-401. |
| 58. | Chen, S. H et al. (April 1994). "Gene Therapy for Brain Tumors: Regression of Experimental Gliomas by Adenovirus-Mediated Gene Transfer <i>In Vivo</i> ," <i>Proc. Natl. Acad. Sci.</i> 91:3054-3057. |
| 59. | Coligan, J. E. et al. (1991). <i>Current Protocols in Immunology</i> . John Wiley & Sons, Inc. 10 pages total. (Table of Contents of Volumes 1-3 only). |
| 60. | Collier, I. E. et al. (May 1988). "H-ras Oncogene-transformed Human Bronchial Epithelial Cells (TBE-1) Secrete a Single Metalloprotease Capable of Degrading Basement Membrane Collagen," <i>The J. of Biol. Chem.</i> 263(14):6579-6587. |

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|-----|--|
| 61. | Docherty, A. J. P. et al. (November 1985). "Sequence of Human Tissue Inhibitor of Metalloproteinases and its Identity to Erythroid-Potentiating Activity," <i>Nature</i> 318:66-69. |
| 62. | Eckman, E.A. et al. (August 1999). "In Vitro Transport of Active α_1 -Antitrypsin to the Apical Surface of Epithelia by Targeting the Polymeric Immunoglobulin Receptor," <i>Am. J. Respir. Cell Mol. Biol.</i> 21:246-252. |
| 63. | Edlund, T. et al. (November 1985). "Cell-Specific Expression of the Rat Insulin Gene: Evidence for Role of Two Distinct 5' Flanking Elements," <i>Science</i> 230:912-916. |
| 64. | Edwards, D.A. et al. (June 1997). "Large Porous Particles for Pulmonary Drug Delivery," <i>Science</i> 276:1868-1871. |
| 65. | Ferkol, T. et al. (March 2000). "Transport of Bifunctional Proteins Across Respiratory Epithelial Cells Via the Polymeric Immunoglobulin Receptor," <i>Am. J. Respir. Crit. Care Med.</i> 161(3):944-951. |
| 66. | Fiers, W. et al. (May 1978). "Complete Nucleotide Sequence of SV40 DNA," <i>Nature</i> 273:113-120. |
| 67. | Francis, S. E. et al. (1994). "Molecular Characterization and Inhibition of a <i>Plasmodium Falciparum</i> Aspartic Hemoglobinase," <i>The EMBO J.</i> 13(2):306-317. |
| 68. | Freshney, R. I., ed. (1987). <i>Animal Cell Culture: A Practical Approach</i> . IRL Press at Oxford University Press. pages ix-xiv. (Table of Contents). |
| 69. | Gait, M. J. ed., (1984). <i>Oligonucleotide Synthesis: A Practical Approach</i> . IRL Press at Oxford University Press. pp.vii-xii., (Table of Contents). |
| 70. | Gasson, J. C. et al. (June 1985). "Molecular Characterization and Expression of the Gene Encoding Human Erythroid-Potentiating Activity," <i>Nature</i> 315:768-771. |
| 71. | Goeddel, D.V. (1990). "Gene Expression Technology," In <i>Methods in Enzymology</i> , Academic Press, Inc. San Diego 185:v-ix. (Table of Contents). |
| 72. | Gottesman, S. (1990). "Minimizing Proteolysis in <i>Escherichia Coli</i> : Genetic Solutions," <i>Methods in Enzymology</i> . J. N. Abelson and M. I. Simon, eds., Academic Press, Inc. 185:118-129. |
| 73. | Guyene, T. T. et al. (December 1976). "Inhibition of Human Plasma Renin Activity by Pepstatin," <i>The J. of Clin. Endocrinol. and Metab.</i> 43(6):1301-1306. |
| 74. | Heinzel, R. et al. (1986). "Molecular Cloning and Expression of cDNA for Human Antileukoprotease from Cervix Uterus," <i>Eur. J. Biochem.</i> 160: 61-67. |
| 75. | Hercz, A. (April 1985). "Proteolytic Cleavages In α_1 -Antitrypsin and Microheterogeneity," <i>Biochem. and Biophys. Res. Comm.</i> 128(1):199-203. |
| 76. | Huang, W. et al. (1996). "Folding and Characterization of the Amino-Terminal Domain of Human Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) Expressed at High Yield in <i>E. Coli</i> ," <i>FEBS Lett.</i> 384:155-161. |
| 77. | Huff, J. R. (August 1991). "HIV Protease: A Novel Chemotherapeutic Target for AIDS," <i>J. of Med. Chem.</i> 34(8):2305-2314. |

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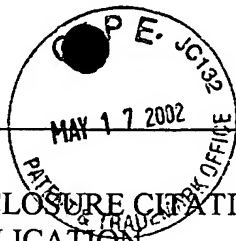
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78.	Jupp, R. A. (July 1990). "The Selectivity of Statine-Based Inhibitors Against Various Human Aspartic Proteinases," <i>Biochem. J.</i> 265:871-878.
79.	Lin, T. Y. and Williams, H. R. (December 1979). "Inhibition of Cathepsin D by Synthetic Oligopeptides," <i>J. Biol. Chem.</i> 254(23):11875-11883.
80.	Kessel, M. and Gruss, P. (July 1990). "Murine Development Control Genes," <i>Science</i> 249:374-379.
81.	Kubo, T. et al. (December 1988). "Location of a Region of the Muscarinic Acetylcholine Receptor Involved in Selective Effector Coupling," <i>FEBS Lett.</i> 241(1,2):119-125.
82.	Kurachi, K. et al. (November 1981). "Cloning and Sequence of cDNA Coding for α_1 -Antitrypsin," <i>Proc. Natl. Acad. Sci.</i> 78(11):6826-6830.
83.	Kurjan, J. and Herskowitz, I. (October 1982). "Structure of a Yeast Pheromone Gene (MF α): A Putative α -Factor Precursor Contains Four Tandem Copies of Mature α -Factor," <i>Cell</i> 30:933-943.
84.	Matteucci, M. D. and Caruthers, M. H. (1981). "Synthesis of Deoxyoligonucleotides on a Polymer Support," <i>J. Am. Chem. Soc.</i> 103(11):3185-3191.
85.	McElvaney, N. G. et al. (October 1992). "Modulation of Airway Inflammation in Cystic Fibrosis: In Vivo Suppression of Interleukin-8 Levels on the Respiratory Epithelial Surface by Aerosolization of Recombinant Secretory Leukoprotease Inhibitor," <i>The J. of Clin. Inves.</i> 90:1296-1301.
86.	Merrifield, R. B. (July 1963). "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide," <i>J. Amer. Chem. Soc.</i> 85:2149-2154.
87.	Metzger, D. et al. (July 1988). "The Human Oestrogen Receptor Functions in Yeast," <i>Nature</i> 334:31-36.
88.	Miller, J. H. and Calos, M. P., eds. (1987). "Gene Transfer Vectors for Mammalian Cells," <i>In Current Communications in Molecular Biology</i> . Cold Spring Harbor Laboratory. pp. vi-ix. (Table of Contents)
89.	Morishima, H. et al. (May 1970). "The Structure of Pepstatin," <i>The J. of Antibiot.</i> 23(5):263-265.
90.	Mullis, K. B. et al. (1994). <u>The Polymerase Chain Reaction</u> . Birkhäuser, Boston, pp.xv-xvii. (Table of Contents).
91.	Murphy, G. et al., eds. (August 1991). "The N-Terminal Domain of Tissue Inhibitor of Metalloproteinases Retains Metalloproteinase Inhibitory Activity," <i>Biochemistry</i> 30(33):8097-8102.
92.	Murray, E. E. et al. (1989). "Codon Usage in Plant Genes," <i>Nucleic Acids Res.</i> 17(2):477-498.
93.	Nakajima, K. and Powers, J. C. (May 1979). "Mapping the Extended Substrate Binding Site of Cathepsin G and Human Leukocyte Elastase: Studies with Peptide Substrates Related to the α_1 -Protease Inhibitor Reactive Site," <i>The J. of Biol. Chem.</i> 254(10):4027-4032.
94.	Otlewski, J. et al. (1999). "Protein Inhibitors of Serine Proteinases," <i>Acta Biochimica Polonica</i> 46(3):531-565.
95.	Pearson, W. R. and Lipman, D. J. (April 1988). "Improved Tools for Biological Sequence Comparison," <i>Proc. Natl. Acad. Sci.</i> 85:2444-2448.

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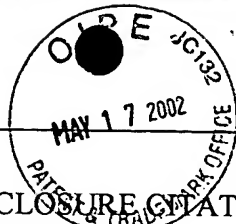
Mailing Date May 10, 2002

96.	Pennington, M. W. et al. (1990). <u>Twenty-First European Peptide Symposium</u> . Gimet E. and Andrew D, eds. Escom; Leiden, Netherlands, pgs. xvii-li. (Table of Contents).
97.	Pinkert, C. A. et al. (1987). "An Albumin Enhancer Located 10 kb Upstream Functions Along with its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice," <i>Genes & Dev.</i> 1:268-276.
98.	Potempa, J. et al. (June 1994). "The Serpin Superfamily of Proteinase Inhibitors: Structure, Function, and Regulation," <i>The J. of Biol. Chem.</i> 269(23):15957-15960.
99.	Queen, C. and Baltimore, D. (July 1983). "Immunoglobulin Gene Transcription Is Activated by Downstream Sequence Elements," <i>Cell</i> 33:741-748.
100.	Sambrook, J. et al. (1989). <u>Molecular Cloning: A Laboratory Manual 2nd ed.</u> Cold Spring Harbor Laboratory Press, Vol. 1-3., pp. xi-xxxviii. (Table of Contents).
101.	Scopes, R. K. (1982). <u>Protein Purification: Principles and Practice</u> . Springer-Verlag, N.Y. pp. xiv-xiii. (Table of Contents).
102.	Smith, D. B. and Johnson, K.S. (1988). "Single-Step Purification of Polypeptides Expressed in <i>Escherichia Coli</i> as Fusions with Glutathione S-Transferase," <i>Gene</i> 67:31-40.
103.	Stevenson-Stetler, W. G. et al. (August 1990). "Tissue Inhibitor of Metalloproteinases-2 (TIMP-2) mRNA Expression in Tumor Cell Lines and Human Tumor Tissues," <i>The J. of Biol. Chem.</i> 265(23):13933-13938.
104.	Teshima, T. et al. (May 1982). "A New Class of Heterocyclic Serine Protease Inhibitors," <i>The J. of Biol. Chem.</i> 257(9):5085-5091.
105.	Turk, V. and Bode, W. (July 1991). "The Cystatins: Protein Inhibitors of Cysteine Proteinases," <i>FEBS Lett.</i> 285(2):213-219.
106.	Umezawa, H. et al. (May 1970). "Pepstatin, A New Pepsin Inhibitor Produced By Actinomycetes," <i>The J. of Antibiot.</i> 23(5):259-262.
107.	Vogelmeier, C. et al. (1990). "Aerosolization of Recombinant SLPI to Augment Antineutrophil Elastase Protection of Pulmonary Epithelium," <i>J. Appl. Physiol.</i> 69(5):1843-1848.
108.	Wada, K. et al. (1992). "Codon Usage Tabulated from the GenBank Genetic Sequence Data," <i>Nucleic Acids Res.</i> 20:2111-2118.
109.	Weir, D. M., eds. <u>Handbook of Experimental Immunology in Four Volumes</u> . L.A. Herzenberg and C. Blackwell co-eds., Blackwell Scientific Publications, Oxford, Total pages 27. (Table of Contents for Volumes 1-4).
110.	Wilde, C. G. et al. (1994). "Cloning and Characterization of Human Tissue Inhibitor of Metalloproteinases-3," <i>DNA and Cell Biol.</i> 13(7):711-718.
111.	Wilhem, S. M. et al. (October 1987). "Human Skin Fibroblast Stromelysin: Structure, Glycosylation, Substrate Specificity, and Differential Expression in Normal and Tumorigenic Cells," <i>Proc. Natl. Acad. Sci.</i> 84:6725-6729.

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| 112. | Willenbrock, F. et al. (1993). "The Activity of the Tissue Inhibitors of Metalloproteinases Is Regulated by C-Terminal Domain Interactions: A Kinetic Analysis of the Inhibition of Gelatinase A," <i>Biochemistry</i> 32(16):4330-4337. |
| 113. | Winoto, A. and Baltimore, D. (1989). "A Novel, Inducible and T Cell-Specific Enhancer Located at the 3' End of the T Cell Receptor α Locus," <i>The EMBO Journal</i> 8(3):729-733. |
| 114. | Woessner, F. J., Jr. (May 1991). "Matrix Metalloproteinases and Their Inhibitors in Connective Tissue Remodeling," <i>The FASEB J.</i> 5:2145-2154. |

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